

1 We claim:

1 1. An oral dosage form, comprising :
2 a bi-layer tablet consisting of a first layer having a first surface and an opposing second
3 surface and a second layer having a first surface and an opposing second surface, wherein said
4 second surface of said first layer physically contacts said first surface of said second layer;
5 an encapsulant disposed over said bi-layer tablet;
6 wherein said first layer comprises an orally therapeutically effective dose of oxycodone
7 HCl in combination with dextromethorphan HBr, wherein the ratio of oxycodone HCl to
8 dextromethorphan HBr is 1:5 by weight;
9 and wherein said oral dosage form does not include an opioid antagonist.

1 2. The oral dosage of claim 1, wherein said encapsulant comprises an outer surface
2 and a first aperture portion extending inwardly through said outer surface and through said
3 encapsulant; and
4 wherein said first layer includes a second aperture portion extending through said first
5 surface inwardly into said first layer.

1 3. The oral dosage of claim 1, wherein said first layer comprises about 9 milligrams
2 of oxycodone and about 45 milligrams dextromethorphan.

1 4. The oral dosage of claim 1, wherein said first layer comprises about 5 milligrams
2 of oxycodone and about 25 milligrams dextromethorphan.

1 5. The oral dosage of claim 4, further comprising polyvinylpyrrolidone dispersed in
2 said first layer.

1 6. The oral dosage of claim 5, further comprising:
2 a carbomer disposed in both said first layer and said second layer;

3 magnesium stearate disposed in both said first layer and said second layer; and
4 microcrystalline cellulose disposed in both said first layer and said second layer.

1 7. A method to provide pain relief to a patient in need thereof, comprising preparing
2 an oral dosage form comprising:

3 a bi-layer tablet consisting of a first layer having a first surface and an opposing second
4 surface and a second layer having a first surface and an opposing second surface, wherein said
5 second surface of said first layer physically contacts said first surface of said second layer;

6 an encapsulant disposed over said bi-layer tablet, wherein said encapsulant comprises an
7 outer surface;

8 wherein said first layer comprises an orally therapeutically effective dose of oxycodone
9 HCl in combination with dextromethorphan HBr, wherein the ratio of oxycodone HCl to
10 dextromethorphan HBr is 1:5 by weight;

11 and wherein said oral dosage form does not include an opioid antagonist.

1 8. The method of claim 7, wherein said encapsulant comprises an outer surface,
2 further comprising the steps of:

3 forming said encapsulant to include a first aperture extending inwardly through said outer
4 surface and through said encapsulant;

5 forming said first surface of said first layer to include a second aperture extending
6 through said first surface inwardly into said first layer.

1 9. The method of claim 7, further comprising the steps of:

2 dispersing about 9 milligrams of oxycodone in said first layer; and

3 dispersing about 45 milligrams dextromethorphan in said first layer.

1 10. The method of claim 7, further comprising the steps of:

2 dispersing about 5 milligrams of oxycodone in said first layer; and

3 dispersing about 25 milligrams dextromethorphan in said first layer.

1 11. The method of claim 10, further comprising the step of dispersing
2 polyvinylpyrrolidone in said first layer.

1 12. The method of claim 11, further comprising the steps of:

2 dispersing a carbomer in both said first layer and said second layer;

3 dispersing magnesium stearate in both said first layer and said second layer; and

4 dispersing microcrystalline cellulose in both said first layer and said second layer.

1 13. A method to prepare an oral dosage form, comprising the steps of:

2 providing oxycodone;

3 providing dextromethorphan;

4 forming a bi-layer tablet consisting of a first layer having a first surface and an opposing
5 second surface and a second layer having a first surface and an opposing second surface, wherein
6 said second surface of said first layer physically contacts said first surface of said second layer;

7 providing an encapsulant;

8 coating said bi-layer table with said encapsulant, wherein said encapsulant comprises an
9 outer surface;

10 wherein said first layer comprises an orally therapeutically effective dose of oxycodone
11 HCl in combination with dextromethorphan HBr, wherein the ratio of oxycodone HCl to
12 dextromethorphan HBr is 1:5 by weight;

13 and wherein said oral dosage form does not include an opioid antagonist.

1 14. The method of claim 13, wherein said forming a bi-layer table step further
2 comprises forming said first surface of said first layer to include a first aperture portion
3 extending through said first surface inwardly into said first layer; and
4 wherein said coating step further includes forming a second aperture portion extending
5 inwardly through said outer surface and through said encapsulant to communicate with said first
6 aperture portion.

1 15. The method of claim 13, further comprising the steps of:
2 dispersing about 9 milligrams of oxycodone in said first layer; and
3 dispersing about 45 milligrams dextromethorphan in said first layer.

1 16. The method of claim 13, further comprising the steps of:
2 dispersing about 5 milligrams of oxycodone in said first layer; and
3 dispersing about 25 milligrams dextromethorphan in said first layer.

1 17. The method of claim 4, further comprising the step of dispersing
2 polyvinylpyrrolidone in said first layer.

1 18. The method of claim 17, further comprising:
2 dispersing a carbomer in both said first layer and said second layer;
3 dispersing magnesium stearate in both said first layer and said second layer; and
4 dispersing microcrystalline cellulose in both said first layer and said second layer.